

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

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Serial No.: To be assigned Group Art Unit: To be assigned

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For: HELICOBACTER FELIS VACCINE

Corresponding to: EP00/202565.8, filed July 17, 2000

PRELIMINARY AMENDMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

July 17, 2001

Sir:

IN THE CLAIMS:

Please cancel claims 1-22 without prejudice or disclaimer of
the subject matter thereof.

Please add the following new claims 23-54:

What is claimed is:

23. A nucleic acid molecule comprising a nucleotide sequence encoding two subunit polypeptides of a urease complex such as expressed by *Helicobacter felis*, said nucleotide sequence having at least 85% homology with SEQ ID NO: 1 or a part thereof encoding at least an immunogenic fragment of one of said subunits, said part having a length of at least 40 nucleotides.

24. The nucleic acid molecule of claim 23, wherein said part has a length of at least 45 nucleotides.

25. The nucleic acid molecule of claim 23, wherein said part has a length of at least 50 nucleotides.

26. The nucleic acid molecule of claim 23, which encodes one or both of the urease X subunit polypeptide and the urease Y subunit polypeptide.

27. The nucleic acid molecule of claim 23, wherein the nucleotide sequence has at least 90% homology with SEQ ID NO: 1.

28. The nucleic acid molecule of claim 27, wherein the nucleotide sequence has at least 94% homology with SEQ ID NO: 1.

29. The nucleic acid molecule of claim 27, wherein the nucleotide sequence has at least 97% homology with SEQ ID NO: 1.

30. DNA fragment comprising a nucleotide sequence according to claim 23.

31. A recombinant DNA molecule comprising a nucleotide sequence according to claim 23 under the control of a functionally linked promoter.

32. A live recombinant carrier comprising a recombinant DNA molecule of claim 31.

33. A host cell comprising a nucleic acid molecule of claim 23, a DNA fragment of claim 30, a recombinant DNA molecule of claim 31 or a live recombinant carrier of claim 32.

34. A *Helicobacter felis* urease X subunit polypeptide, said polypeptide comprising an amino acid sequence that is at least 85% homologous to SEQ ID NO: 2, or an immunogenic fragment of said polypeptide having a length of at least 40 amino acids, wherein said immunogenic fragment induces an immune response against ureaseXY.

35. The polypeptide of claim 34, wherein the immunogenic fragment of said polypeptide has a length of at least 45 amino acids.

36. The polypeptide to claim 34, wherein the immunogenic

fragment of said polypeptide has a length of at least 50 amino acids.

37. The polypeptide of claim 34, wherein said amino acid sequence is at least 90% homologous to SEQ ID NO: 2, or an immunogenic fragment of said polypeptide which induces an immune response against ureaseXY.

38. The polypeptide of claim 31, wherein said amino acid sequence is at least 94% homologous to SEQ ID NO: 2, or an immunogenic fragment of said polypeptide which induces an immune response against ureaseXY.

39. The polypeptide of claim 37, wherein said amino acid sequence is at least 97% homologous to SEQ ID NO: 2, or an immunogenic fragment of said polypeptide which induces an immune response against ureaseXY.

40. A *Helicobacter felis* urease Y subunit polypeptide, said polypeptide comprising an amino acid sequence that is at least 85% homologous to SEQ ID NO: 3, or an immunogenic fragment of said polypeptide having a length of at least 40 amino acids, wherein said immunogenic fragment induces an immune response against ureaseXY.

41. The polypeptide of claim 40, wherein the immunogenic fragment of said polypeptide has a length of at least 45 amino

acids, wherein said immunogenic fragment induces an immune response against ureaseXY.

42. The polypeptide of claim 40, wherein the immunogenic fragment of said polypeptide has a length of at least 50 amino acids, wherein said immunogenic fragment induces an immune response against ureaseXY.

43. The polypeptide of claim 40, wherein said amino acid sequence is at least 90% homologous to SEQ ID NO: 3, or an immunogenic fragment of said polypeptide which induces an immune response against ureaseXY.

44. The polypeptide of claim 43, wherein said amino acid sequence is at least 94% homologous to SEQ ID NO: 3, or an immunogenic fragment of said polypeptide which induces an immune response against ureaseXY.

45. The polypeptide of claim 43, wherein said amino acid sequence is at least 97% homologous to SEQ ID NO: 3, or an immunogenic fragment of said polypeptide which induces an immune response against ureaseXY.

46. A vaccine for combating *Helicobacter felis* infections, comprising an immunogenically effective amount of a nucleic acid molecule of claim 23, a DNA fragment of claim 26, a recombinant

DNA molecule of claim 27, a live recombinant carrier of claim 28, a host cell of claim 29 or a polypeptide according to claims 34 or 40, and a pharmaceutically acceptable carrier.

47. The vaccine of claim 46, further comprising an adjuvant.

48. The vaccine of claim 46, further comprising an additional antigen derived from a virus or microorganism which is pathogenic to mammals.

49. The vaccine of claim 48, wherein said virus or microorganism pathogenic to mammals is selected from the group of Feline Infectious Peritonitis virus, Feline Immune deficiency virus, Canine and Feline Parvovirus, Distemper virus, Adenovirus, Calicivirus, *Bordetella bronchiseptica*, *Borrelia burgdorferi*, *Leptospira interrogans*, *Chlamydia* and *Bartonella henseli*.

50. A vaccine for combating *Helicobacter felis* infections, comprising antibodies against a polypeptide of claims 34 or 40.

51. A method for preparing a vaccine of claim 46, comprising admixing a polypeptide of claims 34 or 40 with a pharmaceutically acceptable carrier.

52. A diagnostic test for the detection of *Helicobacter*

felis specific DNA, comprising a nucleic acid molecule of claim 23, or a fragment thereof.

53. A diagnostic test for the detection of antibodies against *Helicobacter felis*, comprising a polypeptide or a fragment thereof according to claims 34 or 40.

54. A diagnostic test for the detection of antigenic material of *Helicobacter felis*, comprising antibodies against a polypeptide or a fragment thereof according to claims 34 or 40.


TELETYPE

REMARKS

Claims 1-22 are canceled and claims 23-54 are added, hereby.
Claims 23-54 are presented for examination. These amendments are presented to conform the language of the claims to accepted U.S. patent practice, to eliminate multiple dependencies, to recite particular embodiments and to claim additional aspects of the invention disclosed in the specification without limiting the scope of the claims as first written and not for reasons of patentability under 35 U.S.C. 101, 102, 103 or 112.

It is believed that claims 23-54 recite a patentable improvement in the art. Favorable action is solicited. In the event any fees are required with this paper, please charge our Deposit Account No. 02-2334.

Respectfully submitted,


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